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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,896	11/24/2003	Roberto Celeste Ercole Solari	674525-2007	8692

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EXAMINER

CARLSON, KAREN C

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/720,896	Applicant(s) SOLARI ET AL.	
	Examiner Karen Cochrane Carlson, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

1 to at least 138. Claim 1-27, 32, 34, 35, 36, drawn to conjugate of a transport protein and a polypeptide modulator of Notch signaling, classified in class 530, subclass 350.

Applicants will choose the modulator of Notch signaling from the following group:

Notch
Epstein Barr Virus protein
Dominant negative Notch signal repressor
Inhibitor of expression of Notch signal repressor
Inhibitor of activity of Notch signal repressor
Notch signaling transcription factor
Inhibitor of Notch signaling
Dominant negative version of Notch signaling activator
Dominant negative version of Notch signaling transducer
Inhibitor of the expression of Dominant negative version of Notch signaling activator
Inhibitor of the activity of Dominant negative version of Notch signaling activator
Inhibitor of the expression of Dominant negative version of Notch signaling transducer
Inhibitor of the activity of Dominant negative version of Notch signaling transducer
Downregulator of expression of Notch
Downregulator of expression of Notch ligand
Downregulator of expression of downstream component of Notch signaling
Downregulator of activity of Notch **NOTE** that "downregulation" is of expression and not activity
Downregulator of activity of Notch ligand
Downregulator of activity of downstream component of Notch signaling
Toll-like receptor
Bone morphogenic protein
Bone morphogenic protein receptor
Activin

Applicants will additionally choose the transport protein selected from the following group:

Nuclear localization protein
Herpes virus VP22
Homeodomain from Antennapedia
Homeodomain from Fushi tarazu
Homeodomain from Engrailed
HIV tat protein

139 to at least 276. Claims 1-31, 33, drawn to conjugate comprising polynucleotide encoding a transport protein and a polypeptide modulator of Notch signaling, classified in class 536, subclass 23.1.

Applicants will choose the polynucleotide encoding the modulator of Notch signaling from the following group:

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Notch

Epstein Barr Virus protein
Dominant negative Notch signal repressor
Inhibitor of expression of Notch signal repressor
Inhibitor of activity of Notch signal repressor
Notch signaling transcription factor
Inhibitor of Notch signaling
Dominant negative version of Notch signaling activator
Dominant negative version of Notch signaling transducer
Inhibitor of the expression of Dominant negative version of Notch signaling activator
Inhibitor of the activity of Dominant negative version of Notch signaling activator
Inhibitor of the expression of Dominant negative version of Notch signaling transducer
Inhibitor of the activity of Dominant negative version of Notch signaling transducer
Downregulator of expression of Notch
Downregulator of expression of Notch ligand
Downregulator of expression of downstream component of Notch signaling
Downregulator of activity of Notch **NOTE** that "downregulation" is of expression and not activity
Downregulator of activity of Notch ligand
Downregulator of activity of downstream component of Notch signaling
Toll-like receptor
Bone morphogenic protein
Bone morphogenic protein receptor
Activin

Applicants will additionally choose polynucleotide encoding the transport protein selected from the following group:

Nuclear localization protein
Herpes virus VP22
Homeodomain from Antennapedia
Homeodomain from Fushi tarazu
Homeodomain from Engrailed
HIV tat protein

Claim 1 is written so broadly that it is meaningless. Claim 1 is not a proper linking claim because the components within the term "modulator of Notch signaling" differ in structure and in function, as do the members of the term "transport protein". Thus, Claim 1 represents an improper Markush group.

Therefore, Applicants will choose a conjugate comprising one modulator of Notch signaling and one transport protein from Invention 1-138, OR a polynucleotide encoding a conjugate comprising one modulator of Notch signaling and one transport protein from

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Inventions 139-276. This is not a species election, but an election of patentably distinct conjugates or polynucleotides encoding these conjugates.

If the Examiner finds that the elected conjugate or polynucleotide encoding a conjugate is free of the prior art and is enabled, the Examiner will rejoin the polypeptide conjugate and polynucleotide encoding the conjugate.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention 139-276 are related to the protein of Invention 1-138 by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to

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final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

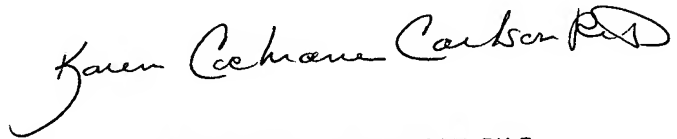
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Karen Cochrane Carlson" followed by a stylized monogram or initials.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER